

07/323665


**UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/323,665	04/24/89	REDDY	V IGHETERODIME
			EXAMINER
			WANG, G
		ART UNIT	PAPER NUMBER
		184	//
DATE MAILED:			03/13/91

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 This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined    ☐ Responsive to communication filed on \_\_\_\_\_    ☐ This action is made final.

 A shortened statutory period for response to this action is set to expire Three (3) month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.      | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____   |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 16 and 18-26 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 16 and 18-26 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

**EXAMINER'S ACTION**

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In accordance with 37 CFR 1.126, claims presented as 18-27 by the amendment C of February 28, 1990 have been renumbered 16-25 respectively and will be referred to only as renumbered.

Claims 16 and 18-26 remain of record to be examined.

The disclosure is objected to because of the following informalities: In claim 25, it is stated as that "The method of claim 31, ...." as indicated in Amendment C of February 28, 1990, when it might be dependent on claim 24 because there is no claim 31 in the instant application. Appropriate correction is required.

Claims 24-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is the example for failing to particularly point out the subject matter for its incorrect dependence. Since claim 25 is dependent on claim 31 as indicated in Amendment C of February 28, 1990, when it might be dependent on claim 24. It should be particularly pointed out that there is no claim 31 in the instant application. It is assumed that claim 25 is intended to depend on claim 24. In claim 26, it is stated that "said beta subunit is encoded by a second expression vector, distinct from said first expression vector, by which said transformed cell is also transformed". It is not clear about applicants' intention that said transformed cell is also transformed whether by first expression vector or second

expression vector.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 20 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 4,923,805. This is a double patenting rejection.

Claims 16, and 18-19 and 21-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 4,923,805. Although the conflicting claims are not identical, they are not patentably distinct from each other because a mammalian cell transformed either by a first expression vector or by a first and a second expression vectors could produce the same biologically active heterodimeric human FSH in both conditions. Therefore, a method for producing the biological active human fertility hormone FSH by a first (encoding the alpha subunits) and a second (encoding the beta subunits) expression vectors is not patentably distinct from a method for producing the same hormone FSH accomplished by only an expression vector as long as encoding the same sequences of the alpha and beta subunits of said FSH. Moreover, a mammalian cell transformed by a second expression vector comprising a DNA sequence encoding the beta subunit of human FSH also contains such said vector. Both a

transformed mammalian cell and its vector are in a condition of a inseparable entity. Furthermore, a method for producing biologically active heterodimeric human FSH comprises a mammalian cell transformed either by an expression vector or a first and a second expression vectors as disclosed by the instant application.

Claims 18-23 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-4 and 11-13 of U.S. Patent No. 4,840,896. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims the same plasmid as expression vector being autonomously replicating in the same mouse cell under the control of the mouse metallothionein promoter (pRF375 in C127 cells, ATCC CRL 8401) as disclosed by U.S. Patent No. 4,840,896.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The remaining references listed on PTO-892 are cited as further reflecting the state of the art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gian Wang

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whose telephone number is (703) 308-4200.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*G. W.*  
Gian Wang  
February 23, 1991

*JmStone*  
JACQUELINE STONE  
PRIMARY EXAMINER  
ART UNIT 184